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# Outcomes after a Uterine-Sparing Approach to Essure Contraceptive Device Removal

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## ABSTRACT

**Background and Objective:** To analyze long-term effectiveness of a conservative, uterine-sparing approach to laparoscopic Essure removal. Specific outcomes of interest include patient satisfaction, symptom resolution, and subsequent surgical intervention.

**Methods:** A retrospective case series and follow-up survey. Patients who underwent laparoscopic Essure removal without concomitant hysterectomy between January 1, 2016 and December 31, 2019 were identified. Greater than 18 months after removal participants completed a survey assessing outcomes.

**Results:** Twenty-nine patients underwent conservative Essure removal and there were 19 survey respondents. Among survey respondents, the mean length of time from Essure placement to removal was 56.7 months (range 5 – 117), and the mean length of time from removal to survey administration was 48.3 months (range 23 – 63). The most frequently reported symptoms were pain (100%), bleeding (52.6%), headache (42.1%), and dyspareunia (42.1%). Methods for removal included laparoscopic salpingectomy (58.6%), a combined hysteroscopic and laparoscopic approach (34.4%), and cornuectomy (6.9%). Regarding symptom improvement after Essure removal, 47.4% of patients reported total improvement, 36.8% reported almost total improvement, 5.3% reported some improvement, and 10.5% reported no improvement. Most patients (89.5%) reported satisfaction with their surgical results, and only two patients required subsequent surgical intervention for symptom management.

**Conclusions:** Most patients in our cohort reported total or almost total improvement in symptoms almost two years after Essure removal, with low rates of reintervention. A uterine-sparing approach to Essure removal, using laparoscopic and hysteroscopic modalities, may be a feasible and effective approach to addressing Essure-attributed symptoms.

**Key Words:** Essure contraceptive device, Laparoscopy, Sterilization.

## INTRODUCTION

Essure is a nickel-titanium device used to perform hysteroscopic sterilization.[1] When delivered hysteroscopically, it incites tubal fibrosis and eventual occlusion. More than 700,000 women have undergone hysteroscopic sterilization with the Essure device since 2002 when the product was introduced.[1] However, increasing reports of complications and high-profile campaigns by patient groups ultimately lead Bayer to cease distribution in December 2018. The main reported adverse effects include pelvic pain and abnormal uterine bleeding, but a broad range of nonspecific symptoms including fatigue, myalgias, palpitations, and weight gain have also been reported.[2–4] Whether these symptoms are in fact related to the Essure device remains contentious but has led an increasing number of patients to pursue removal of the device.[5]

Data on outcomes of device removal are scarce and mostly limited to small retrospective case series.[3,5–7] One of the largest retrospective studies surveyed patients after elective Essure removal and demonstrated that 75% (24/32) of respondents reported almost total or total improvement in quality of life but just 53.1% (17/32) reported improvement in pelvic pain.[3] It is notable that most of the study population (73%) underwent hysterectomy as their mode of removal rather than a conservative uterine-sparing approach. A prospective study by Chene

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et al. specifically surveyed patients undergoing uterine-conserving laparoscopic removal of Essure and also found an improvement in quality-of-life survey scores.[8] However, 40% of patients had a concurrent uterine procedure such as myomectomy or ablation. Given the increasing number of women desiring Essure removal, more data on outcomes is needed to guide preprocedure patient counseling. Particularly, there is a paucity of data on outcomes following a uterine-sparing conservative approach.

We conducted a retrospective case series and follow-up survey of patients who underwent laparoscopic removal of Essure contraceptive device without concomitant hysterectomy at our institution. The objective is to evaluate symptom resolution and need for subsequent intervention.

## METHODS

We conducted a single-center retrospective case series of all patients who underwent Essure removal by adnexal removal between January 1, 2016 and December 31, 2019. Cases were identified using procedure codes. Patients who underwent Essure removal due to suspected device related adverse effects were included. Exclusion criteria included patients undergoing device removal for an alternate indication and those who underwent hysterectomy.

Patient demographic data and comorbid conditions were collected from the medical record. Data regarding the indication for Essure removal, time between device placement and removal, and the method of Essure removal as well as any concurrent gynecologic procedures were recorded.

Patients were administered a survey by phone at least 18 months after Essure removal. The survey consisted of 8 questions regarding their symptomatology, symptom resolution, and need for subsequent intervention. Patients were asked to consider their primary reason for removal, and degree of resolution of that symptom was subdivided into five categories: total improvement, almost total improvement, some improvement, slight improvement, or no improvement.

STATA was used as the statistical software to run the descriptive statistics on demographics and surgery characteristics. Data was presented as mean and standard deviation (SD) for continuous variables. For categorical and dichotomous variables, it was presented as number and percentage.

## RESULTS

From January 1, 2016 to December 31, 2019, 29 patients underwent conservative Essure removal at our institution. Of these patients, two patients declined to participate in the survey, eight patients were not able to be reached after multiple phone call attempts. Ultimately there were 19 survey respondents, for a response rate of 65.5%. Patient characteristics are described in **Table 1**.

Among survey respondents, the mean age at time of Essure removal was 39.1 years (range 28 – 50 years). Notable comorbid conditions among survey respondents included prior abdominal surgeries (47.4%), anxiety (1.53%), and depression (1.53%); no patients had a prior history of chronic back pain, fibromyalgia, or a pre-operative endometriosis diagnosis. The mean length of time from Essure placement to removal was 56.7 months (range 5 – 117), and the mean length of time from removal to survey administration was 48.3 months (range 23 – 63).

**Table 2** presents characteristics of the procedure for all patients. Over half (58.6%) of patients underwent salpingectomy, which was preceded by salpingostomy with removal of the entire Essure device, confirmed by visual inspection. Ten patients (34.4%) underwent a combined hysteroscopic and laparoscopic approach to device removal. In two of these patients (6.9%), the procedure started with a diagnostic hysteroscopy, which demonstrated that one coil was accessible hysteroscopically and was removed; this was followed by a laparoscopic salpingostomy/salpingectomy for the contralateral coil. In six (20.7%) of the combined procedures, a hysteroscopy was performed secondarily due to device fragmentation during laparoscopic removal via salpingostomy/salpingectomy. Finally, in three (10.3%) it was noted that one coil was not accessible laparoscopically, so a subsequent hysteroscopy was performed with successful hysteroscopic removal of a unilateral coil. Concurrent therapeutic procedures at time of Essure removal were rare and included resection of endometriosis (7.4%, n = 2), salpingoophorectomy (7.4%, n = 2), and hysteroscopic polypectomy (.03%, n = 1). There was no trend in the number of Essure removals by year. The procedures took approximately one hour (mean 68 minutes, SD 27) and were associated with minimal blood loss (mean 16 mL, SD 16) (**Table 2**).

Among survey respondents the most frequently reported Essure-attributed symptom was pelvic pain (100%), followed by bleeding (52.6%), headache (42.1%), and

**Table 1.**
Patient Characteristics

| | All Patients (n = 29) | Survey Respondents (n = 19) |
|---|---|---|
| Mean (standard deviation) Age | 38.9 (5.63) | 39.1 (5.30) |
| Mean (standard deviation) Body Mass Index | 29.7 (5.50) | 28.8 (5.29) |
| Mean (range) length of time (in months) from Essure placement to removal | 56.9 (5 – 132) | 56.7 (5 – 117) |
| Mean (range) length of time (in months) from Essure removal to survey administration | N/A | 48.3 (23 – 63) |
| | **N (%)** | **N (%)** |
| Race | | |
| White | 4 (13.8%) | 1 (5.26%) |
| African American | 1 (3.5%) | 0 (0%) |
| Spanish | 17 (58.6%) | 11 (57.9%) |
| Asian | 0 (0%) | 0 (0%) |
| Other | 3 (10.3%) | 3 (15.8%) |
| Not specified/Patient declined | 3 (10.3%) | 3 (15.8%) |
| Hispanic Black | 1 (3.5%) | 1 (5.3%) |
| Language | | |
| English | 23 (79.3%) | 16 (84.2%) |
| Spanish | 6 (20.7%) | 3 (15.8%) |
| Time from Essure placement to removal (years) | | |
| 0 – 1 | 2 (6.9%) | 1 (5.26%) |
| 1 – 2 | 3 (10.3%) | 3 (15.8%) |
| 2 – 3 | 4 (13.8%) | 4 (21.1%) |
| > 3 | 20 (68.9%) | 11 (57.9%) |
| Parity | | |
| 0 | 0 (0%) | 0 (0%) |
| 1 – 2 | 17 (58.6%) | 10 (52.6%) |
| 3 – 4 | 11 (37.9%) | 8 (42.1%) |
| > 4 | 1 (3.7%) | 1 (5.26%) |
| Comorbid conditions | | |
| Previous abdominal surgeries | 15 (51.7%) | 9 (47.37%) |
| Anxiety | 3 (10.3%) | 2 (10.53%) |
| Migraines | 1 (3.5%) | 1 (5.26%) |
| Depression | 3 (10.3%) | 2 (10.53%) |
| Tobacco use | 2 (6.9%) | 1 (5.3%) |
| Endometriosis | 0 (0%) | 0 (0%) |

dyspareunia (42.1%); additional symptoms prompting removal are listed in **Figure 1**. Most patients identified pelvic pain as the primary reason for seeking removal of the Essure implant (73.6%, n = 14), followed by vaginal bleeding (15.7%, n = 3) (**Figure 2**); one patient each reported an allergy to nickel and skin issues as their primary reason for Essure removal. Secondary symptoms reported included vaginal bleeding, depression, vaginal discharge, and bloating.

**Table 2.**
Surgical Technique

| | (n = 29) |
|---|---|
| Operating Room time in minutes, mean (standard deviation) | 68.0 (26.47) |
| Estimated blood loss in ml, mean (standard deviation) | 16.0 (16.60) |
| Method of Essure device removal | **N (%)** |
| Bilateral salpingectomy | 17 (58.6%) |
| Unilateral salpingectomy and unilateral cornuectomy | 2 (6.9%) |
| Combined hysteroscopic and laparoscopic approach | 10 (34.4%) |
| Diagnostic hysteroscopy first with unilateral coil removal followed by unilateral salpingostomy/salpingectomy | 2 (6.9%) |
| Unilateral salpingostomy/salpingectomy with unilateral hysteroscopic removal due to laparoscopic coil fragmentation | 6 (20.7%) |
| Unilateral salpingostomy/salpingectomy with unilateral hysteroscopic removal due to inaccessible coil | 3 (10.3%) |
| Concurrent therapeutic procedures | |
| Endometriosis resection | 2 (6.9%) |
| Salpingo-oopherectomy | 2 (6.9%) |
| Hysteroscopic polypectomy | 1 (3.4%) |

In reporting symptom improvement after Essure removal, 47.4% (n = 9) of patients reported total improvement, 36.8% (n = 8) reported almost total improvement, 5.3% (n = 1) reported some improvement, and 10.5% (n = 2) reported no improvement (**Figure 3**). Most patients (89.5%, n = 17) reported satisfaction with their surgical results (**Figure 4**), and 90% (n = 17) attributed their symptoms to be directly related to the Essure device. Of the survey respondents, two underwent subsequent treatment of persistent symptoms following Essure removal; one patient underwent hysteroscopic endometrial ablation and one underwent hysterectomy with pathologic confirmation of adenomyosis. No other subsequent intervention was noted.

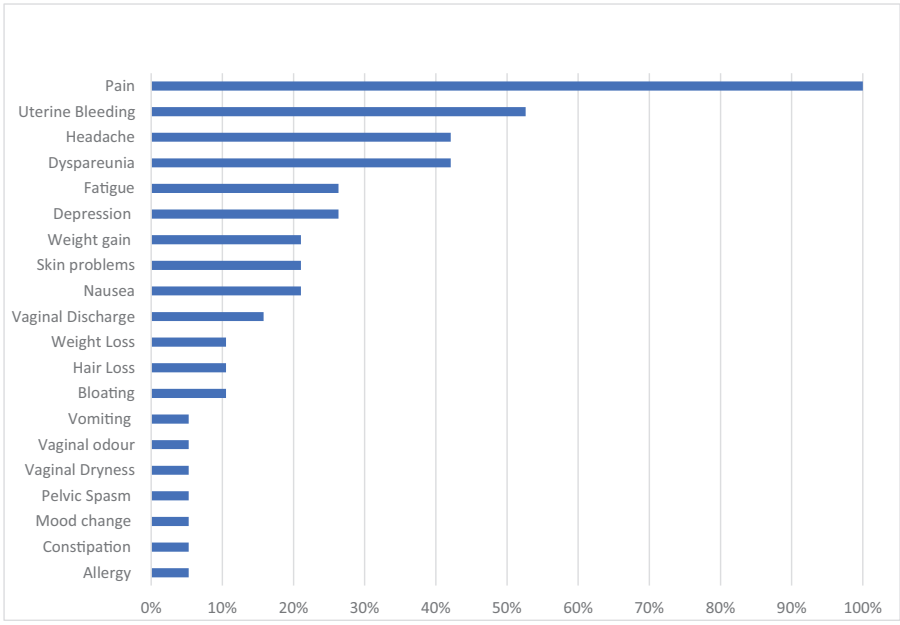


**Figure 1.** Symptoms reported by subjects as attributed to Essure.

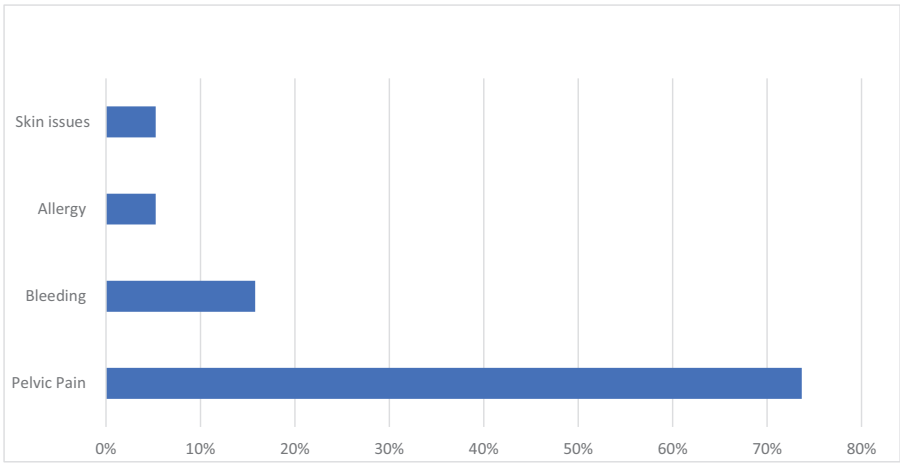


**Figure 2.** Primary symptoms associated with Essure removal.

## DISCUSSION

This study demonstrates that a uterine-sparing approach to Essure removal, using laparoscopic and hysteroscopic modalities, may be a feasible and effective approach to addressing Essure-attributed symptoms. Most patients who underwent Essure removal in our study reported almost total or total improvement in symptoms almost two years after removal.

In contrast to studies that had high rates of hysterectomy for removal, all patients in our study underwent a uterine-sparing approach including salpingectomy (58.6%), hysteroscopic unilateral device removal with laparoscopic unilateral device removal (34.4%), and cornuectomy (6.9%). In the cases of a combined approach, having hysteroscopy available allowed for complete removal while avoiding the increased surgical risks associated with hysterectomy. There were no major surgical complications in our study cohort, and procedures took approximately one hour. Our results support the use of an approach that has few surgical risks, decreased postoperative recovery time, and may be in line with some patients wishes as compared to hysterectomy. Further, we demonstrate a feasible and effective minimally invasive approach can lead to successful Essure removal. In a prospective study by Chene et al., 73.7% of patients underwent minicornuectomy for removal.[8] While this approach was technically successful and resulted in improvement in quality of life in their cohort, due to the need for laparoscopic suturing, the technique may not be able to be as broadly implemented by general gynecologic surgeons.

In our study 84.2% of patients reported a total or near total improvement in symptoms. Further, most patients in our

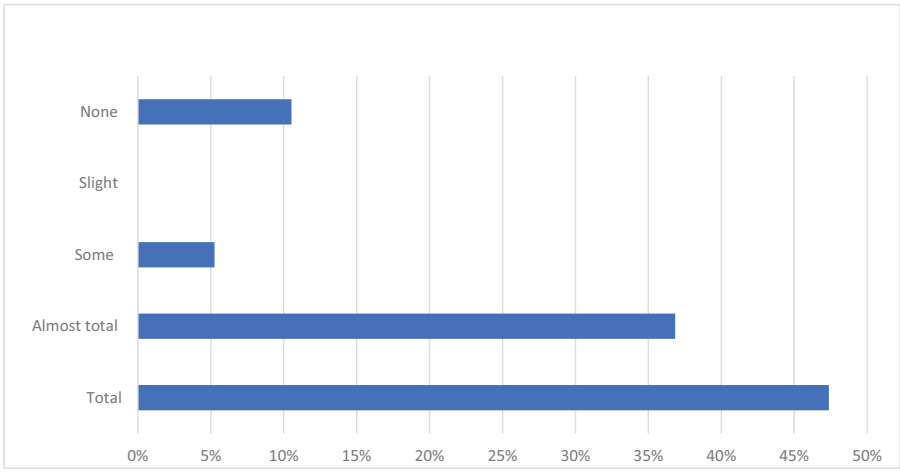


**Figure 3.** Improvement in primary symptoms after Essure device removal.

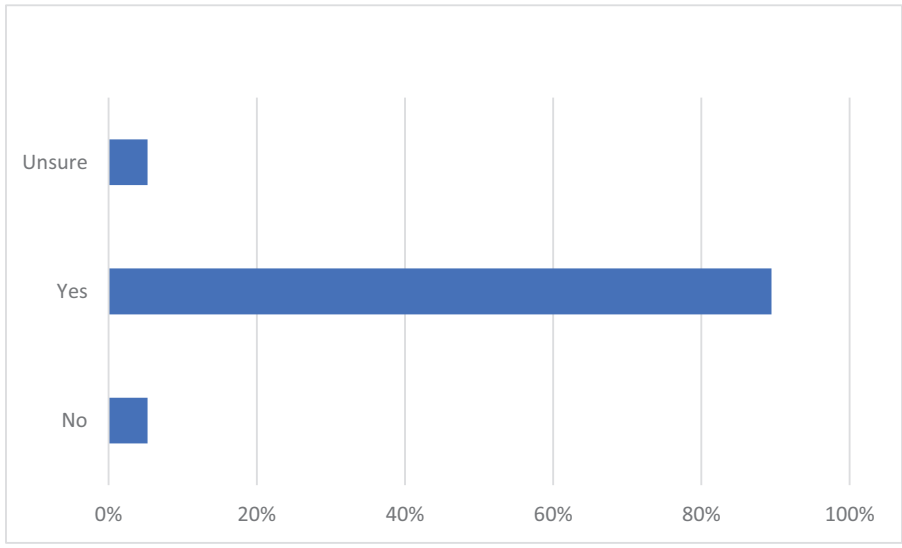


**Figure 4.** Satisfaction with results after Essure removal.

cohort (89.5%) reported satisfaction with their surgical results, and only two patients required subsequent surgical intervention (hysteroscopic ablation and hysterectomy) for symptom management. These results can be compared to the largest case series published to date on symptom resolution after Essure removal, in which 75% of survey respondents reported almost total or total improvement in quality of life, but 31% of patients reported persistent or worsening symptoms.[3] In contrast to our cohort, in the Clark study almost 50% of patients were found to have another possible cause for pelvic pain either intraoperatively or pathologically, including adenomyosis, endometriosis or adhesions. Further, most patients in the Clark cohort (73%) underwent hysterectomy for removal of Essure, which may have accounted for symptom resolution rather than Essure removal itself. We reviewed only those patients undergoing a uterine-sparing procedure to evaluate the effect of the Essure removal procedure, and just five patients underwent a concurrent therapeutic procedure, allowing us to avoid the potential confounder of addressing other potential sources of symptoms surgically. A future study comparing outcomes from those undergoing hysterectomy compared to a uterine sparing approach would provide additional valuable data to guide preoperative counseling.

Among survey respondents, the most frequently reported symptom attributed to Essure was pelvic pain (100%), and most patients (73.6%) identified pelvic pain as the primary reason for seeking removal. Given the complex and multifactorial nature of pelvic pain, it is important to consider other potential etiologies for pain that could influence outcomes. Two patients in our cohort underwent concurrent excision of endometriosis and did not have a pre-operative diagnosis of endometriosis. Four patients had suspected adenomyosis based on ultrasound findings; three of them did not undergo concurrent or subsequent management for adenomyosis, but still noted improvement in symptoms after Essure removal. This supports our conclusion that Essure removal results in favorable outcomes for most patients, and also highlights the importance of a thorough pain evaluation and counseling process prior to Essure removal.

Our case series highlights the risk of coil fragmentation and the importance of ensuring complete device removal. In six patients, coil fragmentation during laparoscopy was noted, which was successfully managed by hysteroscopic removal of the remaining coil fragment. However, in two patients, diagnostic hysteroscopy was performed initially, and the accessible unilateral coil was removed hysteroscopically; this strategy should be considered for coil localization and to minimize the risk of fragmentation. Further, knowledge of the device composition (a stainless-steel inner coil with a terminal ball and a nitinol outer coil with a terminal tab) will allow for gross inspection to ensure comprehensive removal.

Our survey was administered on average 48.3 months after Essure removal, with a range of 23 to 63 months. This follow-up period is longer than any published studies investigating Essure removal outcomes. Chene sought to prospectively evaluate if postsurgical improvement was

sustained, but their follow-up time was limited to six months.[8] Our long follow-up time allows for evaluation of the staying power of postsurgical outcomes and supports a sustained improvement in symptoms in most our cohort.

Our study is the largest series to date examining long term outcomes after a uterine-sparing approach with few confounding concurrent procedures. However, our findings could be strengthened if we had achieved a survey response rate higher than 65.5%. A related limitation includes the opportunity for recall and response bias, which are inherent in the study design, particularly with the intentionally long follow-up period. Another important limitation is participant selection, as those potentially unsatisfied with the results of their procedure may have declined to respond to the survey. We expect this effect to be small; however, as only two patients declined while the remainder of nonresponders were unable to be reached. A large prospective cohort with a long period of follow-up is needed draw stronger conclusions on symptom resolution after removal.

Limited data exists to guide clinicians in the management of patients seeking Essure removal.

Our study adds to the body of evidence by demonstrating favorable outcomes from a uterine-sparing minimally invasive approach to Essure removal, with long-term follow-up and very low rates of re-intervention. The longer follow up time may reflect continued improvement in symptoms over time and can be used to counsel patients on surgical options for removal.

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